SPECIFICATION

TITLE

"IMPLANTABLE MEDICAL DEVICE FOR MEASURING VENTRICULAR PRESSURE"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to an implantable medical device of the type used for measuring ventricular pressure in a subject.

Description of the Prior Art

The pressure of the blood entering the heart is of great interest. All the blood from the veins in the body enters the heart into the right atrium. This represents 95% of the total venous blood volume, the remaining 5% of the volume enter from coronary sinus, which is the return from the hearts own blood supply. The pressure in vena cava, the large vein just outside the heart, is called central venous pressure (CVP). The average level of CVP is just a few mmHg but depending on that the vena cava is very elastic (has high compliance), a small change in pressure indicates that a large volume of blood is involved. The CVP is therefore of great interest because it is an indicator of the blood volume that flows through the veins and enters the heart. The pressure in vena cava will increase if the heart beats too weakly. The increase indicates that the blood is backed up in the veins. The normal response from the heart in this situation is to beat faster and/or increase the stroke volume. There is also another factor that can cause an increase in the CVP resulting from the increase in blood volume when a person lies down, e.g. when he goes to bed at night. The response of the heart is the same as above, i.e. to beat faster and/or increase the stroke volume.

In United States Patent No. 5,040,540 different methods of measuring central venous pressure are disclosed. To obtain a valid central venous pressure a

measurement catheter could be placed within the right atrium or one of the great veins of the thorax (e.g. the superior vena cava, the innominate vein or the subclavian vein).

Measuring in the right atrium should be avoided according to United States Patent No. 5,040,540 due, *inter alia*, to the risk of perforation of the atrial wall.

Pressure sensors adapted to be inserted inside a heart are well known in the art, see e.g. United States Patent Nos. 5,843,135 and 5,324,326.

In United States Patent No. 5,843,135 a piezoelectric pressure transducer is arranged in a patient's heart, e.g. in the right ventricle or right atrium.

United States Patent No. 5,324,326 discloses a pressure sensing pacing lead having a distal pressure sensor for sensing hemodynamic pressure within the heart. The pressure sensor has an integrated circuit chip having a layer of piezo-resistive material and a non-conductive base member.

During diastole, the filling phase of the heart cycle, the tricuspid valve, which is the valve between the right atrium and the right ventricle of the heart, is open. A consequence thereof is that pressure measured in the right ventricle during diastole also reflects the pressure in the right atrium and also the pressure close to the heart in the veins transporting blood into the right atrium (superior vena cava etc.).

United States Patent No. 5,163,429 discloses a hemodynamically responsive system for treating a malfunctioning heart. A signal is developed that is representative of pressure sensed at a site in a patient's circulatory system. This signal may represent e.g. short-term mean right ventricular pressure, mean central venous pressure, right ventricular systolic pressure, or right ventricular diastolic pressure.

In United States Patent No. 5,163,429 as well, a signal representative of the right ventricular systolic pressure is determined by detecting a real time representation of

peak pressure provided that a zero slope condition follows a positive slope. The thus detected peak pressure is shifted into a shift register for further evaluation. Following the determination of the right ventricular systolic pressure it is briefly described that similar circuitry also may be used to determine right ventricular diastolic pressure by using a negative slope detector instead of a positive slope detector. According to the system in United States Patent No. 5,163,429 only a single pressure value (the minimum value) is determined each heart cycle during the diastolic phase. The determined pressure value is then used to obtain short-term or long-term signal representations of right ventricular diastolic pressure.

United States Patent No. 5,368,040 discloses an apparatus and method for monitoring and measuring a number of hemodynamic variables from a single, chronically implanted absolute pressure sensor.

In this known device the first and second derivatives of the pressure signal are used together with the ECG signal to identify start and end points of the systolic and diastolic intervals, respectively.

As shown in Figure 1 in United States Patent No. 5,368,040 the PA systolic pressure is determined by feeding the sensed RV pressure sensor output into a sample and hold circuit that is enabled by the sensing of the R-wave. The systolic pressure is then latched when dP/dt goes negative. The latched value is then held until the next R-wave is sensed.

One drawback with the apparatus described in United States Patent No. 5,368,040 is that information related to the internal EGM signal is required in order to identify specific portions of the heart cycle which renders the apparatus complicated.

A general drawback with the above-described prior art systems is that only limited information of the pressure variation is obtained. No continuous pressure curve of the diastolic pressure is determined.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an implantable medical device which performs a pressure measurement that allows minor pressure variations to be detected as well by using a technically less complicated apparatus.

The above object is achieved in accordance with the principles of the present invention in an implantable medical device having a pressure sensor adapted to be positioned in the right ventricle of the heart to measure the right ventricular pressure and to generate a pressure signal dependent on the measured pressure, a timing unit, supplied with the pressure signal, which identifies the diastolic phase of the heart dependent on the pressure signal, and a processor, also supplied with the pressure signal which determines from the pressure signal, using diastolic timing signals from the timing unit, a diastolic pressure signal which represents the ventricular pressure only during the diastolic phase of the heart cycle.

According to the invention a pressure sensor arranged in the right ventricle of the heart might also be used, in addition to measure the right ventricular pressure, to determine a value representing the central venous pressure in the vena cava.

It is a great advantage to be able to determine the central venous pressure without placing a sensor in the vena cava. It is considered more difficult and thus more expensive to directly measure the pressure in a great vein, e.g. vena cava, because an electrode lead with a pressure sensor becomes more complicated and possibly also more difficult to arrange.

A pressure sensor used in a pacemaker is conventionally arranged on an electrode lead adapted to be place inside the heart, e.g. in the right ventricle or in the right atrium.

The present invention makes it possible to extend the applicability of a pressure signal obtained in the right ventricle or atrium.

According to a preferred embodiment of the present invention the obtained diastolic pressure signal is processed in a median filter in order to achieve a smooth transition between of the curve obtained from diastolic phases from adjacent heart cycles.

DESCRIPTION OF THE DRAWINGS

Figure 1 shows a simplified block diagram of a medical device according to the present invention.

Figure 1a is a block diagram of a further embodiment of a medical device according to the present invention, for administering electrical stimulation therapy.

Figure 2 shows a block diagram of a preferred embodiment of the present invention.

Figure 3 shows a comparison between measured pressure in the right ventricle (RVP) and measured pressure in the vena cava (CVP).

Figure 4 shows a processed curve of the right ventricular pressure (RVP) illustrating the present invention.

Figure 5 shows the curve of the right ventricular pressure (RVP) where the diastolic segments of the curve have been determined according to the present invention.

Figures 6a and 6b show CVP and RVP tracings in order to illustrate the benefits of the median filter.

Figure 7 shows a curve of the amplitude of the right ventricular pressure illustrating how P limit is determined.

Figure 8 shows a curve of the amplitude of the right ventricular pressure derivative illustrating how dP/dt limit is determined.

Figure 9 shows a curve of the amplitude of the right ventricular pressure second derivative illustrating how d^2P/dt_2 limit is determined.

Figure 10 show curves illustrating an alternative way of determining start and end of diastolic phase.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 shows a simplified block diagram of a medical device 2 according to the present invention. The medical device 2 has a pressure sensing arrangement 4 arranged to measure right ventricular pressure of a heart. The pressure sensing arrangement 4 includes a pressure sensor 6 adapted to be positioned in the right ventricle of the heart to measure pressure and to generate a pressure signal 8 in response to the measured pressure. The pressure sensing arrangement 4 also has a pre-processor 10, pressure signal processor 12 and a timing unit 14. The pressure signal processor 12 determines, from the pre-processed pressure signal 16, using diastolic timing signals 18 from the timing unit 14, a diastolic pressure signal representing the ventricular pressure only during the diastolic phase of the heart cycle. One or several threshold values 30, 32 are applied at the timing unit 14 in order to enable the generation of the diastolic timing signals.

Figure 2 shows a block diagram of a preferred embodiment of the present invention. The pressure signal 8 is applied to the pre-processor 10 where the signal is analog-to-digital converted in an A/D converter 22 and filtered in a smoothing filter 24. In the A/D converter 22 the received pressure signal is sampled by a sampling frequency of 100 Hz. The smoothing filter is a fourth order low-pass filter having a border frequency of 15 Hz.

The A/D converted and filtered signal is applied both to the timing unit 14 and to the pressure signal processor 12.

The timing unit 14 has a differentiator 26 and a comparator 28. The signal from the pre-processor is supplied to both differentiator 26 and the comparator 28 in the timing unit 14. The differentiator 26 differentiates the signal that is supplied to the comparator 28. The comparator 28 is provided with two threshold values, "P limit" 30 and "dP/dt limit" 32, that are preset so that the timing unit 14 generates diastolic timing signals 18 at each of the start and end of the diastolic phase of the heart cycle.

Below are some examples of how the thresholds are selected with references to figures 7-9. In figure 10 another approach is illustrated to determine the start and end of the diastolic phase of the heart cycle.

Figure 7 shows the amplitude of the right ventricular pressure (RVP) and a typical P limit of 10 mmHg is marked by the horizontal line. The diastolic phase is identified as the tracings below the line and the start and end points are easily determined as the intersections between the line and the tracing.

Figure 8 shows the amplitude of dRVP/dt and a typical dRVP/dt interval for the absolute value of dRVP/dt being less than 200mmHg/s is marked by horizontal lines.

The diastolic phase is identified as the tracings between the lines and the start and end points are then easily determined.

Figure 9 shows still another possibility wherein the derivative of the dP/dt is determined and used in combination with the pressure signal (figure 7) and/or the derivative of the pressure signal (Figure 8) as threshold values.

Figure 10 illustrates a further enhancement where timing information is used obtained from detection of electrical activity of the heart.

Figure 10 shows schematically how this information may be used:

The upper trace shows the measured pressure (Y-axis line separation being e.g. 20 mm Hg) in the right ventricle and the lower trace (X-axis line separation being e.g. 120 ms) shows the internal EGM measured by a bipolar pacemaker electrode placed in the right ventricle. The heartbeats are detected as the vertical spikes in the IEGM-RV signal. This information can be used to block the pressure detector in for instance the time interval 100 — 250 ms after the detection. These time intervals are shown as the thick lines in the lower trace as being the systolic time interval.

Again referring to Figure 2, the diastolic timing signals are applied to a control unit 34 in the pressure signal processor 12 that controls a shift register 36 to which the pre-processed pressure signal 16 is supplied.

The shift register 36 is a First In First Out (FIFO) register where measurement data are shifted in during diastole detection. The register contains only samples of right ventricular pressure (RVP) during diastole. The end of one diastole interval is merged to the beginning of the next interval.

The data registered in the shift register are then supplied to a median filter 38 that generates the diastolic pressure signal 20 which is the median filtered version of

the continuously detected diastole intervals. Between the intervals the last data in an interval is hold and a smooth merge to the next (adjacent) diastolic segment (interval) is obtained by using a median filtering technique (see e.g. United States Patent No. 5,871,509). The output diastolic pressure signal is the median value of e.g. the last 9 samples of smoothed pressure signal.

In order to illustrate the benefits of using a median filter 38, Figures 6a and 6b show the CVP calculated from the RVP and the RVP without (Figure 6a) and with (Figure 6b) using a median filter, respectively. In Figure 6a the RVP signal is much more erratic whereas in Figure 6b a smooth transition between the different heart cycles is accomplished.

The control unit 34 controls the different parts of the pressure sensing arrangement by providing sample clock signals and control signals 40 to the pre-processor 10, timing unit 14 and to the shift register 36 and the median filter 38. In order to simplify the illustration of the preferred embodiment in Figure 2 these clock signals and control signals are not shown. The control unit 34 also communicates with other control units arranged in the medical device 2.

In order to illustrate the basic principles underlying the present invention Figure 3 shows a comparison between measured pressure in the right ventricle (RVP) and measured pressure in the vena cava (CVP). As can be seen in Figure 3 the lower parts of the RVP, the pressure during diastole, essentially coincide with CVP.

Figure 4 shows the curve of the right ventricular pressure (RVP), the same as in Figure 3. In Figure 4 the two measured pressure curves shown in Figure 3 have been compared and curve segments where the RVP is within 3 mmHg from the CVP

have been marked with a thick line. It is clear from Figure 4 that the RVP during the diastolic phase of the heart cycle coincides to a high degree with the CVP.

Figure 5 shows the curve of the right ventricular pressure (RVP), the pressure signal 8 in Figures 1 and 2. The pressure signal is supplied to the pressure sensing arrangement 4 of the medical device 2 according to the present invention and a diastolic pressure signal 20 has been generated in response thereto. In figure 5 the diastolic segments of the RVP have been marked with a thick line.

In an embodiment of the present invention shown in Figure 1a, the medical device 2 is an implantable heart stimulator which provides therapy in the form of electrical stimulation. The medical device 2 then, in addition to the pressure sensing arrangement further has a stimulation signal generator and therapy control logic 44. The diastolic pressure signal 20 is applied to the control logic 44 that controls, in response to the diastolic pressure signal, the generation of electrical stimulation from the stimulator signal generator 46. The generated electrical stimulation is supplied to heart tissue via one or more electrode 48 leads in accordance with established stimulation techniques.

The electrical stimulation generator can generate pacing pulses, in which case the therapy control logic 44 is pacing logic, or can generate defibrillation pulses, in which case the therapy control logic 44 is, or includes, fibrillation detection logic, or can generate cardioversion pulses, in which case the therapy control logic is, or includes, arrhythmia detection logic.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all

changes and modifications as reasonably and properly come within the scope of their contribution to the art.